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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/600,129

06/19/2003

Sarah S. Bacus

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EXAMINER

HOLLERAN, ANNE L

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

11/13/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/600,129	Applicant(s) BACUS ET AL.	
	Examiner ANNE L. HOLLERAN	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 1-28 and 35-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/22; 6/22; 6/29; 7/21</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-38 are pending. Claims 1-28 and 35-38, drawn to non-elected inventions, are withdrawn from consideration. Claims 29-34 are pending and examined on the merits.

New Grounds of Rejection:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 is indefinite because it is not clear what the metes and bounds of “an optical density less than 9” for a quantitative immunohistochemistry assay. It is not clear from the specification whether the cut-off of 9 for optical density is dependent on the particular assay used in the working embodiments, and also whether this optical density cut-off is specific to the particular equipment for measuring optical density used in the working embodiments.

Claim Rejections Maintained:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 29, 31 and 33 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hudziak (US 5,770,195; issued Jun. 23, 1998) in view of Esteva (Esteva, F. J. et al., Pathology Oncology Research, 7(3): 171-177, 2001), in view of Pinkas-Kramarski (Pinkas-Kramarski, R. et al, Oncogene, 16: 1249-1258, 1998), and further in view of Hoffmann (Hoffmann, M., et al., Cancer Immunol. Immunother., 47(3): 167-175, 1998; abstract only). This is a new grounds of rejection because Pinkas-Kramarski and Hoffmann are cited in addition to Hudziak, and Esteva.

Applicants' arguments have been carefully considered, but fail to persuade. The claimed methods comprise two active steps: that of assaying for the expression level of HER3 in cells from a cancer and the second step of treating the subject with an EGFR antibody if the HER3 expression levels detected have an OD less than 9 when determined by quantitative

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immunohistochemistry that the subject is treated. In light of the new grounds of rejection the claims are more broadly interpreted to read on detection of Her3 expression levels in addition to the step of administering an anti-EGFR antibody. The rejection is maintained because the prior art suggests a method comprising administering an anti-EGFR antibody to a population of patients with a low Her3 level because the prior art teaches that both EGFR growth pathways, as well as Her2/Her3 (ErbB2/ErbB3) pathways are known to contribute to growth and survival of cancers. Therefore, targeting cancers where one pathway activity is low, i.e. ErbB2/ErbB3 pathway, which would be determined by measuring expression levels of ErbB3, is not novel and unobvious over the prior art of record.

Claims 29-34 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hudziak (US 5,770,195; issued Jun. 23, 1998) in view of Esteva (Esteva, F. J. et al., Pathology Oncology Research, 7(3): 171-177, 2001), in view of Pinkas-Kramarski (Pinkas-Kramarski, R. et al, Oncogene, 16: 1249-1258, 1998), in view of Hoffmann (Hoffmann, M., et al., Cancer Immunol. Immunother., 47(3): 167-175, 1998; abstract only), and further in view of Yang (Yang, X.-D. et al., Critical Reviews in Oncology/Hematology, 38: 17-23, 2001). This is a new grounds of rejection because Pinkas-Kramarski and Hoffmann are cited in addition to Hudziak, Esteva and Yang.

Applicants' arguments have been carefully considered, but fail to persuade. The claimed methods comprise two active steps: that of assaying for the expression level of HER3 in cells from a cancer and the second step of treating the subject with an EGFR antibody if the HER3 expression levels detected have an OD less than 9 when determined by quantitative

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immunohistochemistry that the subject is treated. In light of the new grounds of rejection the claims are more broadly interpreted to read on detection of Her3 expression levels in addition to the step of administering an anti-EGFR antibody. The rejection is maintained because the prior art suggests a method comprising administering an anti-EGFR antibody to a population of patients with a low Her3 level because the prior art teaches that both EGFR growth pathways, as well as Her2/Her3 (ErbB2/ErbB3) pathways are known to contribute to growth and survival of cancers. Therefore, targeting cancers where one pathway activity is low, i.e. ErbB2/ErbB3 pathway, which would be determined by measuring expression levels of ErbB3, is not novel and unobvious over the prior art of record.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
November 9, 2009
/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643